

REMARKS

I. Status Summary

Claims 1-4, 9-11, 13, 14, 19, 26, 27, 31, 33, 36-40, 43-45, 48-50, 53-55, 65, and 66 are pending in the present application and have been examined.

The Telephone Interview Summary has been objected to upon the contention that it is inaccurate and contained arguments that were not considered.

Claims 1, 13, 33, 39, 44, 45, 49, and 50 have been objected to on formal grounds relating to the preambles and certain phrases appearing in the claims.

Claims 1, 13, 33, 39, 45, and 50 have been rejected under 35 U.S.C. § 112, second paragraph, upon several contentions that the claims are indefinite.

Claim 65 has been objected to under 37 C.F.R. 1.75 upon the contention that the claim is a substantial duplicate of claim 33. Claim 66 has been objected to under 37 C.F.R. 1.75 upon the contention that the claim is a substantial duplicate of claim 39.

Claims 65 and 66 have been canceled without prejudice.

Claims 1, 3, 4, 9, 13, 26, 33, 39, 44, 45, 49, and 50 have been amended. Applicants respectfully submit that the amendments to claims 1, 13, 33, 39, 44, 45, 49, and 50 are for the purposes of clarity only, and consist of rearranging and/or rephrasing the elements already found in the claims as suggested by the Examiner. As such, applicants respectfully submit that support for the amendments can be found throughout the specification as filed, including particularly in the claims as filed. Additional support can be found on page 6, lines 24-27 (packaging cell line comprises at least one DNA construct encoding a protein required for packaging a retroviral vector; see *a/so* page 11, lines 9-13), at page 13 (description of the reverse transcription event that duplicates the 3' U3 to the 5' end of the double-stranded DNA form of the retrovirus), and at page 11, lines 14-17 (production of retroviral particles by transfecting a retroviral vector into a packaging cell line).

With respect to the amendments to claims 3, 4, 9, and 26, applicants respectfully submit that the only amendments to these claims involves the deletion of the term "functional" from the phrase "functional fragment" that is necessitated by the Examiner's suggestion that the phrase "functional fragment" be amended to "fragment" in the claims

from which claims 3, 4, 9, and 26 ultimately depend (*i.e.*, claims 1 and 13). Applicants respectfully note, however, that both claims 1 and 13 recite the phrase "SDI-1 polypeptide or fragment thereof inhibits cell proliferation". It is believed that the term "functional" could be viewed as redundant, and for clarity, this term was deleted. As such, no subject matter has been surrendered through the deletion of the term "functional". Further, no new matter has been added through the amendments to the claims.

Reconsideration of the application as amended and based on the remarks set forth herein below is respectfully requested.

II. Response to the Objection to the Telephone Interview Summary

Applicants' summary of the interview of May 5, 2005, presented in the Amendment filed June 1, 2005, has been objected to upon the contention that it is inaccurate. According to the United States Patent and Trademark Office (hereinafter the "Patent Office"), the rejections were discussed in general, and possible arguments and possible amendments were discussed, but no agreement was reached with respect to the new matter rejections or the indefiniteness rejections.

Applicants respectfully submit that the Interview Summary presented in the Amendment dated June 1, 2005, reflected applicants' attorneys' understanding of the content of the Interview. In light of the instant objection and the Patent Office's contentions in the pending Official Action, it is respectfully submitted that any apparent mistaken understanding was inadvertent. It is respectfully submitted that there was no intention to mischaracterize the proceedings and outcomes of the Telephone Interview, and Examiner Wilson is kindly thanked for noting the apparent misunderstanding

III. Responses to the Objections to the Claims

Claims 1, 13, 33, 39, 44, 45, 49, and 50 have been objected to on several formal bases related to the claim language. According to the Patent Office, these claims could be more clearly written.

While applicants do not necessarily agree that the claims as written are unclear,

in an effort to facilitate the prosecution of the claims, applicants have amended the claims in a manner consistent with the suggestions of the Examiner.

Applicants respectfully submit that the amendments add no new elements to the claims, but rather rearrange elements already recited in the claims, and thus are supported by the claims as written prior to the amendments. Applicants further respectfully submit that in each case, the rearrangement of the elements of the claims is not to be interpreted as a surrender of any subject matter encompassed by the claims prior to the amendments.

Particularly, applicants respectfully submit that the preambles, steps, and elements of the claims have been clarified, the preambles of the method claims are consistent with the steps recited in the methods, and the functional element of the retroviral particle encompassed by the clause "wherein upon infection of a target cell by a recombinant retroviral particle encoded by said retroviral vector, said SDI-1 coding sequence becomes operatively linked to said regulatory element or promoter and said regulatory element or promoter regulates expression of said SDI-1 coding sequence in said target cell" has been recited in a manner such that it is clear that the clause recites a characteristic of the structure of the retroviral particle and does not refer to a step in the methods.

Accordingly, applicants respectfully submit that all of the objections to claims 1, 13, 33, 39, 44, 45, 49, and 50 have been addressed, and thus respectfully request that the objections to these claims be withdrawn at this time. Applicants further respectfully submit that claims 1, 13, 33, 39, 44, 45, 49, and 50 are now in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

IV. The Enablement Rejections

In the previous Official Action, claims 15, 16, 20, 21, 23, 27, 31, 32, 41, 42, 46, 47, 51, 52, 56-59, 61, and 63 were rejected on several bases under the enablement provision of 35 U.S.C. 112, first paragraph. In the currently pending Official Action, all of these rejections appear to have been withdrawn.

Thus, applicants respectfully submit that there are no rejections under the enablement provision of 35 U.S.C. § 112, first paragraph, currently pending.

V. Responses to the Claim Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-4, 9-11, 13, 14, 19, 26, 27, 31, 33, 36-40, 43, 45, 48, 50, and 53-55 have been rejected under 35 U.S.C. § 112, second paragraph, upon the contention that the phrase "upon infection of a target cell by a recombinant retroviral particle encoded by said retroviral vector, said SDI-1 coding sequence becomes operatively linked to said regulatory element or promoter and said regulatory element or promoter regulates expression of said SDI-1 coding sequence in said target cell" renders the claims indefinite. According to the Patent Office, it is unclear if the phrase is describing a function of the retroviral particle made by the producer cell line, the retroviral vector, or the producer cell line. The Patent Office further asserts that it is particularly unclear if the methods of claims 1 and 33 require a step of infecting a target cell or if the phrase is describing a functional element of the retroviral particle. Finally, the Patent Office asserts that the ability of the recombinant retroviral particle to become operatively linked to the regulatory element or promoter as newly amended in claims 1, 13, 33, 39, 45, and 50 is clear in view of applicants' arguments, and that applicants have not addressed this portion of the rejection.

After careful consideration of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

Initially, applicants respectfully submit that it appears that there is a typographical error in the Official Action, and that the Patent Office appears to have intended to state that the ability of the recombinant retroviral particle to become operatively linked to the regulatory element or promoter as newly amended in claims 1, 13, 33, 39, 45, and 50 is not clear in view of applicants' arguments. In an abundance of caution, applicants will address this rejection from the perspective that applicants' arguments have not sufficiently clarified the phrase at issue.

Additionally, applicants respectfully submit that as discussed in more detail

hereinbelow, it is not the retroviral particle that has the ability to become operatively linked to the regulatory element or promoter, but that it is the nucleic acid sequence encoding the SDI-1 polypeptide or fragment thereof that becomes operatively linked to the regulatory element or promoter.

Applicants respectfully submit that claims 1, 13, 33, 39, 45, and 50 have been amended to recite *inter alia* a 3' LTR region comprising a complete or partial U3 deletion and an insertion in place thereof, wherein said insertion comprises a polylinker sequence into which a regulatory element or a promoter has been cloned, such that upon infection of a target cell by said recombinant retroviral particle, said regulatory element or promoter becomes operatively linked to said nucleic acid sequence and regulates expression of said nucleic acid sequence in said target cell.

Thus, applicants respectfully submit that it is clear that the phrase relates to the structure of the retroviral vector, and hence of the retroviral particle itself, and to the promoter conversion event described in the instant specification at page 13.

Applicants respectfully submit that the phrase at issue does not recite a step in the claimed methods. Rather, the phrase is recited in the relevant claims to describe a feature of the retroviral vectors, and hence the retroviral particles: namely, that the SDI-1 coding sequences are not operatively linked to a promoter in the retroviral vector or particle, but that the SDI-1 coding sequences and the regulatory element or promoter are positioned so that they become operatively linked as a result of reverse transcription after the retroviral particles infect a host cell.

Accordingly, applicants respectfully submit that the rejection of claims 1-4, 9-11, 13, 14, 19, 26, 27, 31, 33, 36-40, 43, 45, 48, 50, and 53-55 under 35 U.S.C. § 112, second paragraph, has been addressed, and respectfully request that it be withdrawn at this time. Applicants further respectfully submit that claims 1-4, 9-11, 13, 14, 19, 26, 27, 31, 33, 36-40, 43, 45, 48, 50, and 53-55 are now in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

VI. Response to the Double Patenting Objections

Claims 65 and 66 have been objected to under 37 CFR 1.75 upon the contention that the claims are substantial duplicates of claims 33 and 39, respectively. Applicants respectfully submit that claims 65 and 66 were added in the prior amendment in an attempt to overcome various objections and rejections of claims 33 and 39 related to the claim language employed therein. As the current amendments are believed to address all outstanding issues with respect to claims 33 and 39, claims 65 and 66 have been canceled without prejudice.

Applicants respectfully submit that the subject matter of claims 65 and 66 is encompassed within amended claims 33 and 39, and thus as such, the cancellation of claims 65 and 66 is not to be interpreted as a surrender of subject matter of claims 65 and 66.

Accordingly, applicants respectfully submit that the objections to claims 65 and 66 have been rendered moot, and respectfully request that they be withdrawn at this time.

CONCLUSIONS

In light of the above amendments and remarks, applicants respectfully submit that claims 1-4, 9-11, 13, 14, 19, 26, 27, 31, 33, 36-40, 43-45, 48-50, and 53-55 are in condition for allowance at this time, and respectfully solicit a Notice of Allowance to that effect.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

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DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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